



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097444,067	11/19/99	MURPHY	B 17634-000512

020350 HM22/0110  
TOWNSEND AND TOWNSEND AND CREW  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO CA 94111-3834

EXAMINER

BRUMBACK, B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/444,067

Applicant(s)  
Murphy et al.

Examiner  
Brenda Brumback

Group Art Unit  
1642



☒ Responsive to communication(s) filed on Dec 4, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 63-78, 88-122, 128-145, and 147-161 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 63-78, 88-122, 128-145, and 147-161 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

### **DETAILED ACTION**

1. This action is responsive to the amendment filed 12/04/2000. Claims 79-87, 123-127, 146, 162, and 163 were canceled. Claims 63, 70, 71, 73, 74, 88, 122, 129, 132, 133, 139, 140, 141, and 147 were amended. Pending claims are 63-78, 88-122, 128-145, and 147-161.
2. Pursuant to the interview of November 6, 2000 and applicant's arguments filed 12/04/2000, the previous restriction requirement is withdrawn in view of the new restriction requirement with election of species which follows:

#### ***Election/Restriction***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 63-69, 88-95, 108-114, 119-122, 128-138, 147-150, and 156-161, drawn to recombinant respiratory syncytial virus (RSV) with a gene deletion, classified in class 424, subclass 211.1.
  - II. Claims 70-78 and 139-145, drawn to recombinant RSV with a modification of one or more nucleotides that modulate gene expression (knock-out mutants), classified in class 424, subclass 211.1.
  - III. Claims 63, 96-107, 115-118, 128, 131, and 151-155 drawn to chimeric RSV, classified in class 424, subclass 199.1.

Art Unit: 1642

It is noted that claims 63, 128, and 131 appear in more than a single group. These claims will be examined with the elected group to the extent that they read on that group.

4. The inventions are distinct, each from the other because of the following reasons:

The viruses of Groups I-III have different structures and different immunological properties. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 63-69, 88-95, 108-114, 119-122, 128-138, 147-150, and 156-161 are generic to a plurality of disclosed patentably distinct species comprising,

- Recombinant RSV with a deletion in the G protein,
- Recombinant RSV with a deletion in the F protein,
- Recombinant RSV with a deletion in the SH protein,
- Recombinant RSV with a deletion in the N protein,
- Recombinant RSV with a deletion in the P protein,
- Recombinant RSV with a deletion in the L protein,
- Recombinant RSV with a deletion in the M2(ORF1) product,
- Recombinant RSV with a deletion in the M2(ORF2) product,
- Recombinant RSV with a deletion in the M protein,

Art Unit: 1642

Recombinant RSV with a deletion in the NS1 protein,

Recombinant RSV with a deletion in the NS2 protein,

Recombinant RSV with a deletion in a gene specifying a change in growth characteristics  
in culture,

Recombinant RSV with a deletion in a gene specifying a change for small plaque size,

Recombinant RSV with a deletion in a gene specifying a change in attenuation in vivo,

Recombinant RSV with a deletion in a gene specifying a change in temperature sensitivity,

Recombinant RSV with a deletion in a gene specifying a change in cold-adaptation,

Recombinant RSV with a deletion in a gene specifying a change in host range restriction.

Recombinant RSV with a deletion in a gene specifying a change in antigen expression,

Recombinant RSV with a deletion in a gene specifying a change in immunogenicity,

Recombinant RSV incorporating an attenuating mutation present within cpts RSV 248,

Recombinant RSV incorporating an attenuating mutation present within cpts  
RSV 248/404,

Recombinant RSV incorporating an attenuating mutation present within cpts  
RSV 248/955,

Recombinant RSV incorporating an attenuating mutation present within cpts RSV 530,

Recombinant RSV incorporating an attenuating mutation present within cpts  
RSV 530/1009,

Art Unit: 1642

Recombinant RSV incorporating an attenuating mutation present within cpts  
RSV 530/1030,

Recombinant RSV incorporating an attenuating mutation present within RSV B-1  
cp52/2B5,

Recombinant RSV incorporating an attenuating mutation present within RSV B-1 cp-23,

Recombinant RSV incorporating an attenuating mutation specifying an amino acid  
substitution at Val267 in the N gene,

Recombinant RSV incorporating an attenuating mutation specifying an amino acid  
substitution at Glu 218 and/or Thr523 in the F gene,

Recombinant RSV incorporating an attenuating mutation specifying an amino acid  
substitution at Cys319, Phe521, Gln831, Met1169, Tyr1321, and/or His 1690 in the L gene,

Recombinant RSV incorporating an attenuating mutation specifying an amino acid  
substitution in the gene-start sequence of M2,

Recombinant RSV incorporating a temperature sensitive amino acid substitution in the  
gene-start sequence of M2,

Recombinant RSV further modified to incorporate a modification of a cis-acting  
regulatory sequence,

Recombinant RSV further modified to incorporate a molecule encoding a cytokine,

Recombinant RSV further modified to incorporate a molecule encoding a T-helper  
epitope, and

Art Unit: 1642

Recombinant RSV further modified to incorporate a molecule encoding a microbial pathogen protein.

6. Claims 70-78 and 139-145 are generic to a plurality of disclosed patentably distinct species comprising,

Recombinant RSV with a reduced or ablated NS2 gene and

Recombinant RSV with a reduced or ablated G gene.

7. Claims 63, 96-107, 115-118, 128, 131, and 151-155 are generic to a plurality of disclosed patentably distinct species comprising

Human chimeric RSV,

Human and bovine or murine chimeric RSV, and

Human chimeric RSV/PIV.

Chimeric RSV with a heterologous G protein,

Chimeric RSV with a heterologous F protein,

Chimeric RSV with a heterologous SH protein,

Chimeric RSV with a heterologous N protein,

Chimeric RSV with a heterologous P protein,

Chimeric RSV with a heterologous L protein,

Chimeric RSV with a heterologous M2(ORF1) protein,

Art Unit: 1642

Chimeric RSV with a heterologous M2(ORF2) protein,

Chimeric RSV with a heterologous NS1 protein,

Chimeric RSV with a heterologous NS2 protein, and

Chimeric RSV with a heterologous M protein.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony



Art Unit: 1642

Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

January 5, 2001

*Brenda Brumback*  
Brenda Brumback,  
Patent Examiner